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UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

SURGICAL INSTRUMENT SERVICE COMPANY, INC.,

Plaintiff/
Counterclaim-Defendant

vs.

INTUITIVE SURGICAL, INC.,

Defendant/
Counterclaimant.

Case No.: 3:21-cv-03496-AMO-LB

UPDATED JOINT CASE MANAGEMENT STATEMENT

Judge: The Honorable Araceli Martínez-Olguín

Case Management Conference: May 30, 2024
Time: 10:00 AM
Courtroom: 10, 450 Golden Gate Ave.,
San Francisco, California

In accordance with Civil Local Rule 16-9, the Standing Order for All Judges of the Northern District of California, Contents of Joint Case Management Statement, Standing Order For Civil Cases Before District Judge Araceli Martínez-Olguín, and the Order Setting Case Management Conference and Statement Deadlines (Dkt. No. 207), Plaintiff Surgical Instrument Service Company, Inc ("SIS") and Defendant Intuitive Surgical, Inc. ("Intuitive") met and conferred regarding the topics set forth in Civil Local Rule 16-9 and by and through their respective attorneys of record, hereby submit the following Updated Joint Case Management Statement (the "Updated Statement"). This Updated Statement updates the following, all of which are attached as exhibits: (1) Joint Case Management Statement dated August 4, 2021 (Dkt. 36); (2) Joint Case Management Statement dated September 21, 2022 (Dkt. 96); (3) Joint Stipulation and Order to Modify Case Schedule (Dkt. 90); (4) Joint Stipulation and Order to Modify Summary Judgment Briefing Schedule (Dkt. 115); and (5) Joint Case Management Statement dated May 31, 2023 (Dkt. 180). *See* Exhibits A-E.

1. Jurisdiction and Service

This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1337(a) and 15 U.S.C. §§ 15, 22, and 1121. The Parties do not dispute personal jurisdiction, venue, or service.

2. Facts

SIS's Statement: The Court has presented the Parties' fundamental factual narratives in its Order Re: Cross Motions for Summary Judgment dated March 31, 2024. (Dkt. No. 204). In addition, the Parties' cross-motions for summary judgment and their arguments at the September 7, 2023 hearing on those motions further elaborated on the Parties' factual narratives. (See Dkt. Nos. 127 at 1-9, 137 at 1-12, and 156 at 1-13).[1]

Intuitive's Statement: Intuitive manufactures innovative medical devices that improve surgical outcomes for patients. The da Vinci system combines the benefits of traditional "open" surgery, such as greater visibility of the surgical field and the ability to perform precise dissections and

[1] There may be additional facts in the record that the Parties may seek to introduce at trial.

reconstructions, with the benefits of minimally invasive surgical techniques. The system uses mechanical arms suspended above the patient to hold a small camera and surgical instruments called EndoWrists, which are inserted into the patient's body through small incisions. The unique design of the EndoWrist, which mimics and even exceeds the range of motion of the human wrist, allows the surgeon to perform minimally invasive operations with great precision. Surgeries performed using da Vinci systems result in reduced trauma, fewer complications, and faster recovery times as compared with other surgical methods, yielding benefits for patients, surgeons, and hospitals.

Intuitive spent tens of millions of dollars developing the da Vinci system and bringing it to market. The system was first introduced for commercial use in the United States in 2000. As a new entrant, Intuitive competed to convince surgeons and hospitals to perform surgeries using the da Vinci that they could otherwise perform using open or laparoscopic surgical techniques. Since then, Intuitive has spent billions developing several new generations of the da Vinci, including the S/Si, the X/Xi, and more recently the da Vinci 5. Intuitive still competes with open and laparoscopic surgical techniques, as well as with other surgical robots and other surgical and non-surgical modes of therapy.

EndoWrist instruments provide superior range of motion through a system of fine wire cables that thread through a complex pulley system. This design gives the surgeon greater flexibility than with a traditional laparoscopic device, but also makes EndoWrists susceptible to wear and tear from repeated use and from undergoing cleaning and sterilization cycles between uses. If an EndoWrist fails during surgery, the risk to the patient can range from minimal (requiring the instrument to be withdrawn from the body and replaced) to serious (if, for example, pieces of the instrument fall into the body) to catastrophic (if, for example, instrument failure leads to unwanted motion while a surgeon is performing a task near a major blood vessel). Given these risks, EndoWrists are designed to be used only a limited number of times and come equipped with a "use counter" that disables the EndoWrist after its final approved use is reached. Intuitive provided the FDA with testing data supporting use limits for the EndoWrists as part of the rigorous clearance process that the da Vinci and EndoWrists were required to undergo before they could be marketed and used on patients.

Intuitive has always made the limits on the use of EndoWrist instruments clear to its customers up front. Da Vinci systems are sold to sophisticated hospitals and medical centers pursuant to

written agreements. Those agreements include clearly disclosed terms that, among other things, prohibit customers from modifying, altering, or misusing the da Vinci system and its components or manipulating the system's software. The agreements also specify that the da Vinci system should be used only with approved instruments and that use of a non-approved instrument may give Intuitive the right to discontinue servicing the system. The use limits on EndoWrist instruments and the terms of Intuitive's contracts that Plaintiffs challenge were in place when Intuitive first began marketing the da Vinci system to customers, long before Intuitive had any supposed power in Plaintiff's alleged market. They were put in place for procompetitive reasons, and not imposed on customers by a supposed monopolist.

Intuitive will not void its service contract with, cease doing business with, or consider it a breach of contract by a customer in the United States who chooses to purchase instruments from a third party so long as they have been cleared by the FDA. The terms of Intuitive's contracts with its customers thus promote patient safety by requiring that surgeries are performed using only approved, unadulterated instruments and properly serviced systems. Each customer who purchased or leased a da Vinci system from Intuitive was fully aware of these contractual provisions at the time of purchase and chose the da Vinci because of the benefits that da Vinci surgery provides to patients, surgeons, and hospitals.

SIS offers repair services for traditional open and laparoscopic surgical instruments. In 2019, SIS began acting as a distributor for a company called Rebotix, which had developed a procedure for modifying EndoWrists for the purpose of defeating the EndoWrist's use counter. The process involved cracking open the housing of EndoWrist instruments compatible with the da Vinci S and Si models, removing the EndoWrist's use counter chip, and soldering the chip to a new circuit board that, when reinserted into the EndoWrist, fools the da Vinci system into accepting a new use count for the instrument starting at zero. SIS and Rebotix are not affiliated with Intuitive, and Intuitive is not privy to any testing protocols, verifications, validations, processes, or quality controls—if any exist—that were used to evaluate the safety of EndoWrists with reset use counters. SIS and Rebotix sold EndoWrists with reset use counters to hospitals without obtaining FDA clearance.

Intuitive became aware that EndoWrists were being modified and reset because it found adulterated use counters in broken EndoWrists that had been returned to Intuitive to be evaluated for replacement. After discovering the modified EndoWrists, Intuitive began reaching out to customers to explain that resetting the use counters could create significant safety concerns for patients and to express Intuitive's view that such modifications required FDA clearance. Intuitive also reminded customers that using unapproved instruments would violate the customers' contracts with Intuitive.

3. Legal Issues

SIS's Statement: The primary legal issues presented in this action are identified in the Court's Order Re: Cross Motions for Summary Judgment. (Dkt. No. 204).

Intuitive's Statement: Intuitive anticipates the following contested legal issues and/or mixed questions of law and fact at trial:

- Whether Plaintiff can establish any relevant antitrust market in which Intuitive has monopoly power or market power;
- Whether Plaintiff can establish that it suffered antitrust injury;
- Whether Plaintiff can establish that Intuitive engaged in any tying arrangement or other exclusionary conduct that was unlawful under the rule of reason;
- Whether Plaintiff is entitled to any damages or any injunctive relief;
- Whether Plaintiff made false or misleading statements that caused harm to Intuitive and/or to competition;
- Whether Plaintiff disrupted Intuitive's contracts with its customers or induced Intuitive's customers to breach their contracts with Intuitive; and
- Whether Intuitive is entitled to any damages or any injunctive relief.

4. Motions

The Court denied Defendant's Motion to Stay on September 28, 2021 (Dkt. No. 61), and denied Defendant's Motion to Dismiss except as to one portion of SIS's Lanham Act claim on November 23, 2021. (Dkt. No. 70).

The Court ruled on the Parties' cross-motions for summary judgment and Intuitive's *Daubert* motions on March 31, 2024.

SIS's Statement: More specifically, the Court dismissed Intuitive's false advertising counterclaims, including Counts One through Four. (Dkt. No. 204 at p. 19). Additionally the Court granted SIS's motion for summary adjudication on Intuitive's affirmative defense of unclean hands. Id. The Court granted in part and denied in part Intuitive's summary judgment motion, dismissing SIS's Lanham Act claim and ruling that SIS's antitrust claims will proceed to trial. Id.

The Court granted in part and denied in part Intuitive's seven *Daubert* motions as to SIS's experts. (Dkt. No. 203 at pp. 26, 30-31). More specifically, the Court denied Intuitive's motions to exclude the testimony of Jean Sargent, Kurt Humphrey, Dr. Amandeep Mahal, Philip J. Phillips, Dr. Russell Lamb, and Richard Bero. Id. The Court granted Intuitive's motion to exclude the portions of Dr. Parnell's testimony about the cause of failure of the EndoWrists he saw at the Rebotix repair facility, but otherwise denied the motion to exclude Dr. Parnell's testimony. Id. at p. 31.

Intuitive's Statement: Intuitive agrees that the Court granted in-part and denied in-part the parties' cross-motions for summary judgment (Dkt. 204). Intuitive does not agree that the Court's summary judgment order dismissed Counts 1 through 4 of Intuitive's counterclaims and Intuitive's unclean hands defense in their entirety. Plaintiff asked the Court to "grant ***partial*** summary judgment on Intuitive's counterclaims 1-4 and its unclean hands affirmative defense ***as they relate to FDA***." (Dkt. 127 at 23:4-6 (emphasis added).) *See also id.* at 19:17-18 (arguing that "any SIS statements that it did not require clearance by the FDA cannot be false or misleading"); *id.* at 21:10-11 ("To the extent that the Court can rule on Intuitive's FDA-related claims, SIS's statements are not false or misleading); *id.* at 22:13-14 ("Finally, for the same reasons that Intuitive cannot prevail on its FDA-related *Lanham Act* claims, SIS cannot possibly have engaged in unclean hands on these FDA issues."). Plaintiff did not move for summary judgment as to any other aspect of Intuitive's counterclaims. Counts 1 through 4 of Intuitive's counterclaims identified several factual bases for those counterclaims unrelated to the issue of FDA clearance, including allegedly false or misleading statements by SIS regarding "the nature, efficacy, and/or safety of the service SIS coordinates," and statements claiming that "devices 'serviced' through SIS had been repaired to meet 'original specifications' of EndoWrists and are safe to use," among others. (Dkt. 75 at 61 ¶ 85.) Likewise, Intuitive's unclean hands defense pleaded that SIS's claims were barred because SIS "acted contrary to applicable FDA regulations ***and/or engaged in other***

misconduct, including tortious interference with Intuitive's contracts and business relationships." (Dkt. 75 at 39 (emphasis added).) And Intuitive's opposition to Plaintiff's motion confirmed that "Intuitive's counterclaims and affirmative defenses" were based on "other false or misleading statements by SIS" that did not relate to the FDA and that those other statements were "not the subject of SIS's motion." (Dkt. 137 at 17 n.12.)

The Court's order granting in-part Plaintiff's motion for summary judgment analyzed only the FDA-related issues that were the subject of Plaintiff's motion and were briefed by the parties. Intuitive respectfully submits that the Court's order cannot reasonably be understood as granting relief that Plaintiff did not seek in its motion and dismissing Counts 1 through 4 of Intuitive's counterclaims and Intuitive's unclean hands defense in their entirety. If necessary, Intuitive will file a formal motion for clarification of the Court's summary judgment ruling to address any ambiguity in the Court's order.

Intuitive also disagrees with Plaintiff's statement regarding the scope of the Court's *Daubert* rulings (Dkt. 203). Intuitive respectfully submits that the Court did not deny Intuitive's motion to exclude the testimony of Philip J. Phillips in its entirety. Rather, the Court granted that motion in-part, excluding Phillips' "opinions that 'SIS is not a remanufacturer, as that term is defined by the FDA' (Phillips Report at Conclusion), and that 'Intuitive Surgical's customer communications alleged in SIS's complaint and court filings are simply false and misleading,'" because those portions of Phillips' testimony were "legal conclusions." (Dkt. 203 at 20:2-6, 21:2-5.)

5. Amendment of Pleadings

The deadline to file amended pleadings has passed. The Parties do not anticipate any amendments of the pleadings.

6. Evidence Preservation

The Parties certify that they have reviewed the Guidelines Relating to the Discovery of Electronically Stored Information ("ESI Guidelines") and have met and conferred pursuant to Fed. R. Civ. P. 26(f) regarding reasonable and proportionate steps taken to preserve evidence relevant to the issues reasonably evident. The Parties have confirmed litigation holds are in place. On April 1, 2022, the Parties filed a Stipulated Order Re: Discovery of Hard-Copy Documents and Electronically Stored Information (Dkt. No. 85), which the Court entered on April 4, 2022 (Dkt. No. 86).

7. Disclosures

The parties fully and timely complied with the initial disclosure requirements of Fed. R. Civ. P. 26(a)(1) on August 26, 2021.

8. Discovery

Fact discovery closed on November 10, 2022 (Dkt. No. 90, Exhibit A at p. 1). February 23, 2023 was the deadline for submission of all expert reports (Dkt. No. 90, Exhibit A at p. 1). As of May 31, 2023, all discovery was completed in this case. (Dkt. No. 180 at p. 5).

Intuitive anticipates that additional discovery may be necessary to update the record relating to events since the deadlines for the completion of fact discovery and merits expert discovery. Intuitive may seek leave to conduct trial depositions, but is not presently moving the Court for such relief. SIS will oppose any additional discovery.

9. Class Action

This is not a class action.

10. Related Cases

Two antitrust class actions brought on behalf of Intuitive's hospital customers (*Larkin*, No. 3:21-cv-03825; and *Franciscan Alliance*, No. 3:21-cv-05198) were filed in 2021. On August 20, 2021, Plaintiffs moved to consolidate those actions[2] and, on August 25, 2021, the Court granted Plaintiffs' consolidation motion and the matters were consolidated in No. 3:21-cv-03825 as *In re: Da Vinci Surgical Robot Antitrust Litigation*, which is pending before this Court.

11. Relief

SIS seeks damages it asserts were caused by Intuitive's violations of the Sherman Act subject to mandatory trebling. 15 U.S.C. § 15. SIS may also seek injunctive relief, including preventing Intuitive from continuing the acts SIS asserts are in violation of the Sherman Act. 15 U.S.C. §§ 1, 2, and 26. SIS also seeks costs, expenses, reasonable attorneys' fees, and post-judgment interest on all sums awarded. 15 U.S.C. § 15(a). Intuitive opposes all forms of relief sought by SIS.

[2] At the time the consolidation motion was filed, there was a third action, brought by then-Plaintiff Kaleida Health. That party, however, filed a notice of voluntary dismissal on January 14, 2022 (Doc. No. 72).

Intuitive seeks damages it asserts were caused by SIS's false and misleading statements and SIS's tortious interference with contract. In addition to damages, Intuitive may also seek disgorgement of profits and injunctive relief, including preventing SIS from making false and misleading statements or interfering with Intuitive's contracts with its customers. Intuitive also seeks costs, expenses, reasonable attorneys' fees, and post-judgment interest on all sums awarded. SIS opposes all forms of relief sought by Intuitive.

12. Settlement and ADR

SIS's Statement: Prospects for settlement are not bright. To date, Intuitive has been unwilling to engage in settlement talks. No ADR plan exists for this matter. From SIS's perspective, discovery being closed, summary judgment having recently been decided, and Intuitive's *Daubert* challenges having been ruled on, there are no pending matters that are necessary to position the parties to negotiate a resolution. In light of this, SIS urges the Court to set the earliest possible trial date.

Intuitive's Statement: SIS's characterization of Intuitive's position with regard to settlement and ADR is not accurate. In prior case management statements, the parties advised the Court, jointly, on these issues as follows:

September 2022: "The parties do not believe additional settlement or ADR efforts would be fruitful at this time." (Dkt. 180-2 at 5.)

May 2023: "To date, based on the respective positions of the parties and the condensed substantive case schedule between November 2022 – May 2023 . . . the parties do not believe ADR would be useful in narrowing the issues in this case or for potentially reaching a resolution." (Dkt. 180 at 7.)

Although Intuitive does not believe that settlement discussions or ADR would be useful in narrowing the issues in the case or for potentially reaching a resolution at the present time, Intuitive is willing to discuss these matters further with SIS and is also willing to engage in ADR prior to trial.

13. Other References

The parties do not believe that this case is suitable for reference to binding arbitration, special master, or the Judicial Panel on Multidistrict Litigation.

14. Narrowing of Issues

In light of the Court's summary judgment and *Daubert* Orders, the Parties will meet and confer in an attempt to narrow issues.

15. Expedited Trial Procedure

The Parties do not believe that this case is appropriate to be handled under the Expedited Trial Procedure of General Order 64.

16. Scheduling

SIS's Statement: A case management conference is scheduled for May 30, 2024. (Dkt. No. 207). The current case schedule (Dkt. No. 90) does not set forth dates for the final pretrial conference and trial. SIS proposes that the final pretrial conference occur on August 22, 2024 at 11AM and trial beginning as soon thereafter as is convenient for the Court.

Intuitive Statement: On May 20, 2024, Intuitive filed a Motion for Reconsideration of certain portions of the Court's summary judgment order in *In re: Da Vinci Surgical Robot Antitrust Litigation* (Intuitive's "Motion for Reconsideration"). If the Court declines to reconsider that order, Intuitive has reserved the right to file a motion for certification of an interlocutory appeal. The resolution of the issues raised in Intuitive's Motion for Reconsideration may impact the presentation of evidence, jury instructions, or other trial-related matters in this case. The nature and extent of such impact may need to be addressed after the Court has ruled on the Motion and/or any interlocutory appeal has been resolved. Intuitive, therefore, respectfully submits that the issues raised in Intuitive's Motion for Reconsideration should be resolved (through reconsideration and/or interlocutory appeal) before this case proceeds to trial.

In any event, Intuitive respectfully requests that a trial date be set no earlier than the second quarter of 2025 in order to provide the parties with adequate time to prepare this case for trial.

17. Trial

SIS's statement: SIS seeks a jury trial on all antitrust claims and issues so triable. SIS estimates that a trial can be conducted in 14 days, excluding jury selection, opening statement, and closing argument. SIS submits that this estimate is entirely realistic in view of the Court's rulings on the parties' cross-motions for summary judgment, wherein SIS's Lanham Act claim was dismissed and Intuitive's false advertising counterclaims (Counts One through Four) were dismissed along with

Intuitive's affirmative defense of unclean hands. (Dkt. No. 204 at p. 19) SIS's case will be limited to its antitrust claims against Intuitive, thus eliminating the need for either party to present fact and expert testimony directed to the now dismissed Lanham Act claim or Intuitive's counterclaims.

Intuitive's Statement: As noted above, Intuitive disagrees with Plaintiff's statement regarding the scope of the Court's summary judgment ruling, and maintains that each of its counterclaims and its defense of unclean hands should be submitted to the jury in this case. With respect to the timing of trial, it is Intuitive's position that trial in this case should not proceed until the issues raised in Intuitive's Motion for Reconsideration in *In re: Da Vinci* have been resolved (through reconsideration and/or interlocutory appeal). Intuitive is not seeking to consolidate trial in this case with the class action in *In re: Da Vinci*, but respectfully submits that the resolution of the issues presented in its Motion for Reconsideration may impact the presentation of evidence in this case and other trial-related matters, including jury instructions.

Once trial is scheduled, Intuitive estimates that a trial in this case can be conducted in twenty (20) trial days, inclusive of seventeen (17) days of testimony and two or three (2-3) additional days for jury selection, opening statements, a jury instruction charge conference, and closing arguments. That estimate reflects Intuitive's understanding that each trial day will commence at 8:30 AM and conclude at 2:00 PM. Intuitive proposes that all trial hours be divided equally between Plaintiff and Intuitive.

18. Disclosure of Non-Party Interested Entities or Persons

The parties have completed filing their "Certification of Interested Entities or Persons" as required by Civil Local Rule 3-15. Dkt. 24, 41.

19. Professional Conduct

All attorneys of record for the parties have reviewed the Guidelines for Professional Conduct for the Northern District of California.

Dated: May 23, 2024

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SURGICAL INSTRUMENT SERVICES

Dated: May 23, 2024

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E-Filing Attestation

I, Joshua Van Hoven, am the ECF User whose ID and password are being used to file this document. In compliance with Civil Local Rule 5-1(i)(3), I hereby attest that each of the signatories identified above have concurred in this filing.

/s/ *Joshua Van Hoven*